

REMARKS**I. PRELIMINARY REMARKS**

Claims 12, 15, 21, 23, 24, 26, 33 and 39 have been amended. Claims 38 and 40 have been canceled. No claims have been added. Claims 1, 3-28, 33 and 36, 37, 39 and 41-48 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes with appreciation that the Examiner has indicated that claims 12-14, 26-28 and 38 are directed to allowable subject matter. As claims 12 and 26 have been rewritten in independent form and the limitations of now-canceled claim 38 have been added to independent claim 33, applicant respectfully submits that claims 12-14, 26-28, 33, 36 and 37 are in condition for allowance.

Applicant respectfully submits that the amendments to claims 15, 21, 23 and 24 have been made solely in order to correct typographical errors. More specifically, the amendment to claim 15 merely results in a consistent reference to the "inflatable, energy transmitting lesion formation element" throughout the claim and the amendments to claims 21, 23 and 24 merely correct a typographical error in the pendency that resulted in claims 21, 23 and 24 depending from dependent claim 19 instead of independent claim 15. Accordingly, it is respectfully submitted that such amendments do not raise new issues and should be entered in accordance with 37 C.F.R. § 1.116(a) and MPEP 714.12 and 714.13.

Applicant filed an Information Disclosure Statement ("IDS") on January 14, 2003. A copy of the IDS, including the PTO form 1449 and date stamped postcard receipt, is attached hereto as Exhibit 1. The Office Action does not include any indication that the IDS has been considered. Accordingly, applicant hereby requests that the Examiner consider the IDS, initial the PTO form 1449 and return it to applicant with the next Office Action.

II. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 5 and 17 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Office Action appeared to question whether or not the claimed microporous material can allow substantially no liquid perfusion therethrough. Applicant respectfully submits that the Examiner's assumption for purposes of examination, i.e. that the microporous material allows substantially no liquid perfusion therethrough, is in fact correct. [See, e.g., the specification at page 11, line 30 to page 12, line 10.] The rejection under 35 U.S.C. § 112 should, therefore, be withdrawn.

III. CLAIMS 1, 3-11 AND 15-25**A. The Rejections**

Claims 1, 3, 5-8, 11, 15-20, 24 and 25 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the U.S. Patent No. 5,047,028 to Qian ("the Qian '028 patent") and U.S. Patent No. 5,255,678 to Deslauriers ("the Deslauriers '678 patent").

Claim 4 has been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Qian '028 patent, the Deslauriers '678 patent and U.S. Patent No. 5,329,923 to Lundquist ("the Lundquist '923 patent").

Claims 9 and 10 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Qian '028 patent, the Deslauriers '678 patent and U.S. Patent No. 5,961,513 to Swanson ("the Swanson '513 patent").

Claims 21-23 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Qian '028 patent, the Deslauriers '678 patent, U.S. Patent No. 5,569,241 to Edwards ("the Edwards '241 patent") and U.S. Patent No. 5,403,311 to Abele ("the Abele '311 patent").

The rejections of claims 1, 3-11 and 15-25 under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

B. Discussion Concerning Claims 1, 3-11 and 15-25

Independent claims 1 and 15 call for respective combinations of elements including, *inter alia*, "a relatively short, relatively stiff shaft" and "an inflatable, **energy transmitting lesion formation element** associated with the distal portion of the shaft that allows substantially no liquid perfusion therethrough." The cited references fail to teach or suggest such a combination.

The Qian '028 patent discloses a device which includes a tube 10 and a balloon 12. In contrast to the claimed combination, the Qian balloon 12 creates thrombosis in blood vessels, not lesions. The Deslauriers '678 patent is directed to a mapping balloon and, accordingly, cannot remedy the deficiencies in the Qian '028 patent.

As the Qian '028 patent and Deslauriers '678 patent fail to teach or suggest the respective combinations of elements recited in independent claims 1 and 15, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 1, 3, 5-8, 11, 15-20, 24 and 25 under 35 U.S.C. § 103 is improper and should be withdrawn.

The Lundquist '923 patent and Swanson '513 patent, which have been cited with respect to dependent claims 4, 9 and 10, fail to remedy the above-identified deficiencies in the Qian '028 patent and Deslauriers '678 patent. For example, the Lundquist '923 patent and Swanson '513 patent do not suggest using a balloon that is designed to create thrombosis in blood vessels for lesion formation. Applicant respectfully submits, therefore, that claims 4, 9 and 10 are patentable for at least the same reasons as independent claim 1 and that the rejections thereof under 35 U.S.C. § 103 should also be withdrawn.

C. Discussion Concerning Claim 24

In addition to the elements recited in independent claim 19, the combination defined by claim 24 calls for a fluid source that "**continuously infuses fluid to and ventilates fluid from** the inflatable, energy transmitting lesion formation element." The cited references fail to teach or suggest such a combination.

For example, the Qian '028 patent merely states that fluid is used to "inflate" and "fill" the balloon 12. [Column 1, lines 44-47 and column 2, lines 10-14.] There is no indication that fluid is continuously infused to and ventilated from the balloon 12. Similarly, to the extent that the mapping electrode teachings of the Deslauriers '678 patent are even applicable to the thrombosis inducing device disclosed in the Qian '028 patent, the Deslauriers balloon is inflated with a syringe 26 and there is no indication that fluid is being continuously ventilated as it is supplied by the syringe.

As the Qian '028 patent and Deslauriers '678 patent fail to teach or suggest the combination of elements recited in claim 24, whether viewed alone or in combination, applicant respectfully submits that the rejection of claim 24 under 35 U.S.C. § 103 should be withdrawn for reasons in addition to those discussed above with respect to independent claim 15.

IV. CLAIMS 39 AND 41-48

A. The Rejections

Claims 39, 41-43 and 45 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,800,484 to Gough ("the Gough '484 patent"). Claims 46-48 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Gough '484 patent, the Edwards '241 patent and the Abele '311 patent.

Claims 39-43 and 45 have been rejected under 35 U.S.C. § 102 as being anticipated by the Qian '028 patent. Claim 44 has been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Qian '028 patent and the

Deslauriers '678 patent. Claims 46-48 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings the Qian '028 patent, the Edwards '241 patent and the Abele '311 patent.

As claim 40 has been canceled, it is respectfully submitted that the rejections thereof under 35 U.S.C. § 102 have been rendered moot. The rejections of the remaining claims under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

B. The Claimed Combinations

Independent claim 39 calls for a combination of elements comprising "a surgical probe including ... an inflatable, energy transmitting therapeutic element" and "a cooling fluid source operably connected to the inflatable, energy transmitting therapeutic element and adapted ... to *continuously infuse and ventilate cooling fluid to and from* the inflatable, energy transmitting therapeutic element." The cited references fail to teach or suggest such a combination.

C. Rejections Based on the Gough '484 Patent

The Gough '484 patent discloses various multiple antenna ablation devices that are configured to deliver conductive fluid to tissue. More specifically, the Gough '484 patent discloses the use of a fluid delivery member 23 "that is sufficiently porous to permit the passage of fluid" as well as an expandable member 29 that may be used in combination with the fluid delivery member to enlarge the fluid delivery member. [Column 6, lines 34-36; and column 6, line 58 to column 7, line 30.] The Gough '484 patent also discloses the use of a "source of conductive medium." [Column 7, lines 8-25.] Although the "source of conductive medium" supplies fluid, it is not used for ventilation because the fluid is delivered to the tissue by way of the fluid delivery member 23.

As the Gough '484 patent fails to teach or suggest each and every element in the combination defined by independent claim 39, applicant respectfully submits that the rejection of claims 39, 41-43 and 45 under 35 U.S.C. § 102 is improper and should be withdrawn.

The Edwards '241 patent and Abele '311 patent, which have been cited with respect to dependent claims 46-48, fail to remedy the above-identified deficiencies in the Gough '484 patent. Applicant respectfully submits, therefore, that claims 46-48 are patentable for at least the same reasons as independent claim 39 and that the rejection thereof under 35 U.S.C. § 103 should also be withdrawn.

D. Rejections Based on the Qian '028 Patent

The Qian '028 patent, as noted above, merely states that fluid is used to "inflate" and "fill" the balloon 12 and there is no indication that fluid is continuously infused to and ventilated from the balloon 12.

As the Qian '028 patent fails to teach or suggest each and every element in the combination defined by independent claim 39, applicant respectfully submits that the rejection of claims 39, 41-43 and 45 under 35 U.S.C. § 102 is improper and should be withdrawn.

Turning to the rejection of claims 44 under 35 U.S.C. § 103, the Deslauriers '678 patent discloses a balloon that is inflated with a syringe 26. There is no indication that fluid is being continuously ventilated as it is supplied by the syringe 26. As such, the Deslauriers '678 patent cannot remedy the deficiencies in the Qian '028 patent. Applicant respectfully submits, therefore, that claim 44 is patentable for at least the same reasons as independent claim 39 and that the rejection of claim 44 under 35 U.S.C. § 103 should also be withdrawn.

The Edwards '241 and Abele '311 patents, which have been cited with respect to dependent claims 46-48, fail to remedy the above-identified deficiencies in the Qian '028 patent. Applicant respectfully submits, therefore, that claims 46-48 are patentable for at

least the same reasons as independent claim 39 and that the rejection thereof under 35 U.S.C. § 103 should also be withdrawn.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

3/13/03
Date

Respectfully submitted,

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**VERSION OF AMENDMENTS TO APPLICATION WITH
MARKINGS TO SHOW CHANGES MADE**

Claims 12, 15, 21, 23, 24, 26, 33 and 39 have been amended as follows:

12. (Twice Amended) A surgical probe [as claimed in claim 1, wherein the shaft defines a distal end, the surgical probe further], comprising:

a relatively short, relatively stiff shaft defining a distal portion, a distal end and a proximal portion;

an inflatable, energy transmitting lesion formation element associated with the distal portion of the shaft that allows substantially no liquid perfusion therethrough; and

a needle slidably mounted within the shaft and movable relative to the shaft such that a distal portion of the needle extends outwardly from the distal end of the shaft, the inflatable, energy transmitting lesion formation element being mounted on the distal portion of the needle.

15. (Amended) A surgical probe system, comprising:

a surgical probe including a relatively short, relatively stiff shaft defining a distal portion and a proximal portion and an inflatable, energy transmitting lesion formation element associated with the distal portion of the shaft that allows substantially no liquid perfusion therethrough; and

a fluid source operably connected to the inflatable, energy transmitting lesion formation [therapeutic] element and adapted to maintain pressure within the inflatable, energy transmitting lesion formation [therapeutic] element at a predetermined level.

21. (Twice Amended) A surgical probe system as claimed in claim [19] 15, further comprising a pressure sensor adapted to determine the pressure within the inflatable, energy transmitting lesion formation element.

23. (Amended) A surgical probe system as claimed in claim [19] 15, wherein the fluid source comprises a pump.

24. (Twice Amended) A surgical probe system as claimed in claim [19] 15, wherein the fluid source continuously infuses fluid to and ventilates fluid from the inflatable, energy transmitting lesion formation element.

26. (Twice Amended) A surgical probe system [as claimed in claim 15, wherein the shaft defines a distal end, the surgical probe further], comprising:

a surgical probe including a relatively short, relatively stiff shaft defining a distal portion, a distal end and a proximal portion and an inflatable, energy transmitting lesion formation element associated with the distal portion of the shaft that allows substantially no liquid perfusion therethrough;

a fluid source operably connected to the inflatable, energy transmitting lesion formation element and adapted to maintain pressure within the inflatable, energy transmitting lesion formation element at a predetermined level; and

a needle slidably mounted within the shaft and movable relative to the shaft such that a distal portion of the needle extends outwardly from the distal end of the shaft, the inflatable, energy transmitting lesion formation element being mounted on the distal portion of the needle.

33. (Twice Amended) A surgical probe, comprising:

a hollow needle; and

a therapeutic assembly, located within the hollow needle and movable relative thereto, including a relatively short shaft defining a distal portion and a proximal portion, [and] an inflatable, energy transmitting therapeutic element associated with the distal portion of the shaft and a hollow stylet movable relative to the relatively short shaft, the relatively short shaft being located within the stylet.

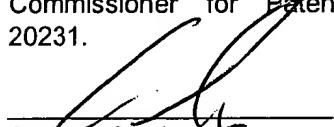
39. (Amended) A surgical probe system, comprising:

a surgical probe including a relatively short shaft defining a distal portion and a proximal portion and an inflatable, energy transmitting therapeutic element associated with the distal portion of the shaft; and

a cooling fluid source operably connected to the inflatable, energy transmitting therapeutic element and adapted to maintain pressure within the inflatable therapeutic element at a predetermined level and to continuously infuse and ventilate cooling fluid to and from the inflatable, energy transmitting therapeutic element.

PATENT

I certify that on 1/14/03, which is the date I am signing this certificate, this correspondence and all attachments mentioned are being deposited in the United States Postal Service as first class in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.


Craig A. Slavin

Applicant: Koblish et al.

Serial No.: 09/737,176

Filing Date: December 13, 2000

Title: Surgical Probe For Supporting Inflatable Therapeutic Devices In Contact With Tissue In Or Around A Body Orifice And Within Tumors

Group Art Unit: 3739

Examiner: Peffley

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-SB08 are being brought to the attention of the examiner for consideration in connection with the examination of the above-identified patent application. Copies of the cited documents are enclosed. It is respectfully requested that the examiner indicate consideration of the cited references by returning a copy of the attached form PTO-SB08 with initials or other appropriate marks, and that the references be made of record as cited references in the application.

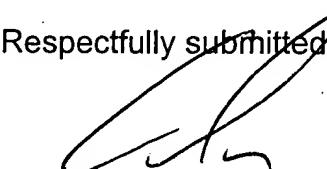
The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), as an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists. The filing of this information disclosure statement shall not be construed as an admission against interest in any manner.

A check in the amount of \$180 is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any

overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

1/11/03
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	<i>Complete if Known</i>	
	Application No.	09/737,176
	Filing Date	12/13/00
	Inventor	Koblish
	Art Unit	3739
	Examiner	Peffley

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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PATENT

Client Name & Docket No. ERT 015916-279
Title: SURGICAL PROSTHESES FOR SUPPORTING . . .
Applicant: KROBLISH
Ser. / Pat. # 09/1737, 170 Filing / Issue Date: 12/13/00

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